

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/936,954	01/24/2002	Parker Small	UF-1561A-US	2929
29847	7590 10/17/2006		EXAM	INER
BEUSSE BROWNLEE WOLTER MORA & MAIRE 390 N. ORANGE AVENUE			ZEMAN, R	OBERT A
<b>SUITE 2500</b>			ART UNIT	PAPER NUMBER
ORLANDO,	FL 32801	•	1645	<del></del>

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
		09/936,954	SMALL ET AL.			
	Office Action Summary	Examiner	Art Unit			
		Robert A. Zeman	1645			
Period fo	The MAILING DATE of this communication apports.	pears on the cover sheet with the c	orrespondence address			
WHIC - Exter after - If NO - Failu Any r	ORTENED STATUTORY PERIOD FOR REPL CHEVER IS LONGER, FROM THE MAILING D nsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statute eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be timwill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status						
1)⊠	Responsive to communication(s) filed on 09 A	Jugust 2006.				
·—	This action is <b>FINAL</b> . 2b) This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
•—	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims					
4)⊠	4)⊠ Claim(s) <u>16</u> is/are pending in the application.					
•	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)	Claim(s) is/are allowed.					
6)⊠	Claim(s) <u>16</u> is/are rejected.					
7)	Claim(s) is/are objected to.					
8)□	Claim(s) are subject to restriction and/o	or election requirement.				
Applicati	on Papers					
9)[	The specification is objected to by the Examine	er.				
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority u	ınder 35 U.S.C. § 119					
,	Acknowledgment is made of a claim for foreign All b) Some * c) None of:		)-(d) or (f).			
	<ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> </ol>					
	3. Copies of the certified copies of the price	•	out in this National Stage			
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
		о по останова ворие не	-			
Attachmen		_				
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)	4) ☐ Interview Summary Paper No(s)/Mail Da				
	mation Disclosure Statement(s) (PTO/SB/08)	5) Notice of Informal F				
	r No(s)/Mail Date	6) 🔲 Other:				

#### **DETAILED ACTION**

The amendment filed on 8-9-2006 is acknowledged. Claim 16 has been amended. Claim 16 is pending and is the sole claim under examination.

### **Objections Maintained**

# Specification

The objection to the specification for the improper use of trademarks is maintained for reasons of record. As outlined previously, the use of the multiple trademarks has been noted in this application (see pages 16-17 and 19-21 for example). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It should be noted that Applicant did not address this objection in his response.

## Claim Rejections Withdrawn

The nonstatutory obviousness-type double patenting rejection of claim 16 over claim 1 of U.S. Patent No. 6,951,730 is withdrawn in light of the Terminal Disclaimer filed on 5-19-2006.

The nonstatutory obviousness-type double patenting rejection of claim 16 over claim 1 of U.S. Patent No. 5,910,421 is withdrawn in light of the Terminal Disclaimer filed on 5-19-2006.

The nonstatutory obviousness-type double patenting rejection of claim 16 over claim 1 of U.S. Patent No. 6,551,791 is withdrawn in light of the Terminal Disclaimer filed on 5-19-2006.

Art Unit: 1645

The provisional nonstatutory obviousness-type double patenting rejection of claim 16 over claim 1 of copending Application No. 11/029,729 is withdrawn in light of the Terminal Disclaimer filed on 5-19-2006.

The rejection of claim 16 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "strong presence" with regard to protein, nitrite and leukocyte esterase level is withdrawn in light of the amendment thereto.

# New Grounds of Rejection

# 35 USC § 112, New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended the claim to recite "... a presence of nitrite and/or a presence of leukocyte esterase activity...". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. Said term, contrary to Applicant's assertion, is not supported by Figure 1 or the table. Moreover, the specification provides no support where bacterial sinusitis can be detected solely on the presence of leukocyte esterase activity.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is rendered vague and indefinite by the use of the phrase "... a presence of nitrite and/or a presence of leukocyte esterase activity...". Based on the punctuation and the transitory term "and/or", it is unclear whether leukocyte esterase activity alone can be used to detect bacterial sinusitis. Consequently, it is impossible to determine the metes and bounds of the claimed invention.

Claim 16 is rendered vague and indefinite by the use of the term "presence" with regard to nitrite and leukocyte esterase level. It is unclear what concentration or activity level is meant to be conveyed by said term since said term is not explicitly defined in the specification.

#### Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Application/Control Number: 09/936,954

Art Unit: 1645

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866.

The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert Navarro can be reached on (571) 272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>.

Application/Control Number: 09/936,954

Art Unit: 1645

Page 6

Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO.

Customer Service Representative or access to the automated information system, call 800-786-

9199 (IN USA OR CANADA) or 571-272-1000.

ROBERT A. ZEMAN PRIMARY EXAMINER

October 10, 2006